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Thursday, March 8, 2007

ENZI SAYS APPROVING BIOLOGICS "PATHWAY" MUST ENSURE SAFETY, INNOVATION; AVOID RACE TO SIMPLY CUT COSTS

Washington, D.C. - U.S. Senator Mike Enzi (R-WY), Ranking Member of the Senate Health, Education, Labor and Pensions (HELP) Committee, today said the rush to open a new regulatory pathway for the Food and Drug Administration (FDA) to approve generic biologics creates a monumental regulatory challenge that should not be a race to cut drug costs alone, but one that also includes a careful effort to protect and promote innovation in the marketplace while still ensuring patient safety.

"Biologics are the skyscrapers of the drug world. They are towering monuments to medicine, science and biotechnology that can't be duplicated without exact blueprints and precision engineering," Enzi said. "Allowing drug makers to duplicate these giants will create an unprecedented regulatory and safety challenge for the FDA. If Congress grants that authority in haste, the results could be disastrous."

Biologics are protein-based, highly-engineered drugs derived from a complicated process. Biologics in common use today include: Humulin, a replacement insulin for diabetics; Procrit, an anemia treatment for cancer patients; and Avonex, a therapy for persons with Multiple Sclerosis.

"Biologics are making it possible for thousands of Americans to live productive lives, while others are changing the way we treat deadly diseases like cancer and infectious diseases," Enzi said, in a HELP Committee hearing to examine proposals to expand FDA's biologics authority. "We need to move diligently and earnestly, but we must not short-circuit safety, leave patients at risk or sacrifice protections that will encourage the drug industry to innovate."

Enzi said he favors taking time to fully consider a range of framework options for allowing generic biologics, such as the European model for follow-on, or generic, biologics. The system already adopted in Europe created an abbreviated approval pathway for biologic drugs but also required due consideration of safety, innovation and savings while also leaving decisions about critical scientific issues to scientists.

Enzi rejected calls to link biologics legislation to the package of FDA-related bills currently being prepared by the HELP Committee, including the "Enhancing Drug Safety

and Innovation Act," the "Prescription Drug User Fee Act" reauthorization, and the "Medical Device User Fee and Modernization Act" reauthorization, which Senators have tagged as must pass bills and targeted for final approval before Congress goes to its August recess.

"There are several must-pass FDA-related reauthorizations that Congress must have approved and sent on their way to the President's desk by August 3rd," Enzi said. "Due to the scientific complexity and uncertainty regarding biologics, premature and ill-considered solutions should not be included in the discussion of those must pass bills."

"If we get this balance wrong, then we face two potential undesirable outcomes – either no new biologics will be available to provide the next cure for the most horrid diseases; or individuals will die as we rush products to market without considering their safety implications," Enzi added.

Over 20 years ago, Congress enacted legislation that provided a framework for the creation of generic drugs. In creating that initial framework, Senator Orrin Hatch (R-UT) and Congressman Henry Waxman (D-CA) and others wrote watershed legislation, which balanced safety and savings in creating an abbreviated pathway for the approval for most prescription drugs. That legislation, referred to as the Hatch-Waxman Act, was the product of careful drafting and consideration over many years.

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Hearing Statement
U.S. Senator Michael B. Enzi (R-WY)

"Follow-on Biologics"

Thank you, Mr. Chairman, for holding this important hearing and beginning an important discussion regarding follow-on biologics. Part of the reason we need to have this hearing today is for us to understand the complex issues surrounding follow-on biologics. It is also a good opportunity to educate the public about the critical and complex nature of the issue. Some will say that it is easy to think about providing a generic version of biologics, just like we provide generic version of drugs. However, that assumes that all drugs are just like biologics. They aren't.

Biologics are very complex molecules modeled after key processes occurring daily within the human body. If a drug was a 3 bedroom, 2 bath starter home, a biologic would be a skyscraper. The size and complexity of the items are just that different.

Unlike drugs which we can describe the structure with a high degree of precision, follow-on biologics elude similar scientific description. So, if I was to try to build the skyscraper of a biologic without the blueprints (as any generic company would need to do to create a follow-on biologic), I would have to ensure that every copy was identical to

the last or there could be fatal results. Thus, we must ensure that the science drives any sort of safety standard. One girder out of place would cause the entire structure to fall.

For all of their complexity, we can only imagine the potential of some of these potential miracle biologics, such as an AIDS vaccine or islet cell therapy to cure diabetes. Today, some biologics are making it possible for thousands of Americans to live productive lives, while others are changing the way we treat deadly diseases like cancer and infectious diseases. In the last twenty years, complex diseases, such as multiple sclerosis and heart disease have been converted from virtual death sentences to manageable chronic conditions with the help of biologic drugs.

Over twenty years ago, Congress enacted legislation that provided a framework for the creation of generic drugs, generic versions of small molecules. In creating that initial framework, Senator Hatch and others crafted the watershed Hatch-Waxman legislation, which balanced innovation, safety, and incentives to create an abbreviated pathway for the approval for small molecule drugs. However, that legislation intentionally did not directly address follow-on biologics because they were too new and too complex to fit within that framework.

Now, we are being asked to find an appropriate framework for the approval of follow-on biologics. In doing so, however, we must acknowledge the differences between drugs and biologics. In addition, any framework must acknowledge safety and preserve the fast pace of innovation.

I urge my colleagues to consider the ramifications of this legislation. If we get this wrong, then we face two potential undesirable outcomes – either new biologics will not be available to provide the next cure for life-threatening diseases or individuals die as we rush products to market without considering their safety implications.

We shouldn't rush a solution through Congress. We must take the time to fully consider other framework options, such as the European model for follow-on biologics. Anytime we start legislating on complex scientific issues and don't know all the facts, we risk endangering lives.

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